DEC 1 7 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
PSA Assay for Bayer ADVIA® Integrated Modular System (IMS)™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K022177

1. Intended Use

The *Bayer ADVIA® IMS* PSA assay is an *in vitro* diagnostic device intended to quantitatively measure prostate specific antigen (PSA) in human serum. This assay is indicated for the measurement of serum PSA as an aid in management (monitoring) of prostate cancer patients. PSA values obtained using the Bayer ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 PSA Assay	T01-3450-51	T03-3541-01

3. Device / Method

Product Name	Reagent Part # / BAN Number	Calibrator Part # / BAN Number
ADVIA IMS PSA Assay	B42-3912-42 / 02598475 (100 tests) 06694045 (250 tests)	B43-3940-01 / 03625840

Imprecision

Within-run and total imprecision were evaluated by testing six calibrator levels and commercial controls. % CV was calculated based on all replicates using one calibration curve.

ADVIA IMS	
Level (ng/mL)	Total CV(%)
2.6	2.7
6.5	1.8
24.1	1.7
99.1	2.0

Immuno 1	
Level (ng/mL)	Total CV(%)
3	3.1
23	3.4
96	2.5

Correlation (Y= ADVIA IMS, X = comparison system)

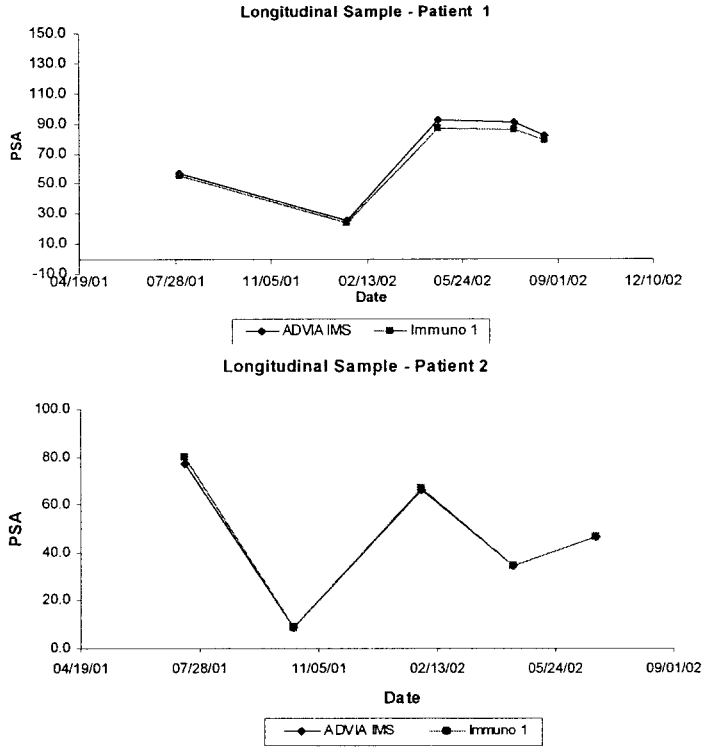
Correlation study was performed with forty four (44) serum samples (0.07 to 62.93 ng/mL).

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	54	0.97 * X – 0.18	0.93	0.999	0.37-79.70
Serum	Immuno 1	44	0.97 * X – 0.06	0.78	0.999	0.07-62.93

	95% Confidence Intervals			
	µg/L	Ng/mL	µg/L	ng/mL
Slope	0.951	0.951	0.981	0.981
Intercept	-0.49	-0.49	0.37	0.37
$S_{y.x}$	0.53	0.53	1.27	1.27

Serial Monitoring

Two examples of serial patient monitoring studies using Bayer ADVIA IMS assay results in comparison to results obtained for another marketed device are shown in the following figures.



Interfering Substances

Serum pool with PSA concentration of 4.0 ng/mL was spiked with hemoglobin, triglyceride, bilirubin, albumin, immunoglobulins, PAP, kallikrein, and drug pools (up to two times lethal dose) and then assayed for PSA. In all cases the observed recovery bias was found to be of no clinical significance.

Interfering Substance	Interfering Substance Concentration		Analyte Concentration		Effect
	SI Units	(mg/dL)	(µg/L)	(ng/mL)	(%)
Hemoglobin	10.0 g/L	1000	2.08	2.08	2.8
Lipids (Triglycerides)	11.3 mmol/L	1000	3.57	3.57	0.1
Bilirubin	428 µmol/L	25	4.05	4.05	0.7
Immunoglobulin (IgG)	60.0 g/L	6000	3.13	3.13	-5.3
Albumin	65.0 g/L	6500	3.05	3.05	-1.3
Cross-Reactivities					
Cross-Reactant	**Cross-Reactant Concentration**		**Analyte Concentration**		**Cross-Reactivity**
	(µg/mL)		(µg/L)	(ng/mL)	(%)
PAP	1.0		3.99	3.99	0.015
Kallikrein (plasma)	1.0		4.23	4.23	0.018
Kallikrin (urine)	1.0		3.86	3.86	0.013
Vincristine Sulfate	13.5		3.82	3.82	0.3
Vinblastine	5.11		3.82	3.82	0.3
Mitomycin C	73		3.86	3.86	1.2
Tamoxifen - Free	60		3.82	3.82	0.3
Tamoxifen - Citrate	60		3.82	3.82	0.3
Etoposide	415		3.82	3.82	0.3

5-Fluorouracil	1600	3.65	3.65	-1.8
Cyclophosphamide Monohydrate	800	3.86	3.86	1.2
Doxorubicin HCl	51.8	3.86	3.86	1.2
Diethylstibestrol	23	3.82	3.82	0.3
Methotrexate	450	3.67	3.67	-0.9
Cis-Platinum	173	3.82	3.82	0.3
Lupron	15	3.59	3.59	2.4
Megestrol Acetate	243	3.86	3.86	1.2

Recovery

Recovery of the PSA dilution in the range of 0.01 to 4.0 ng/mL was evaluated. Recovery ranged from 97 to 104%.

Sample #1

Expected , ng/mL	Observed, ng/mL	Recovery, %
4.31	4.31	100
3.28	3.17	97
2.26	2.23	99
1.23	1.21	99
0.20	0.20	100
	Mean	99

Sample #2

Expected , ng/mL	Observed, ng/mL	Recovery, %
4.27	4.27	100
3.25	3.35	103
2.23	2.24	100
1.21	1.21	100
0.19	0.19	100
	Mean	101

Sample #3

Expected , ng/mL	Observed, ng/mL	Recovery, %
4.58	4.58	100
3.44	3.41	99
2.30	2.28	99
1.16	1.19	103
0.02	0.02	100
	Mean	100

Sample #4

Expected , ng/mL	Observed, ng/mL	Recovery, %
4.38	4.38	100
3.30	3.25	98
2.22	2.24	101
1.14	1.19	104
0.06	0.06	100
	Mean	101

Analytical Range

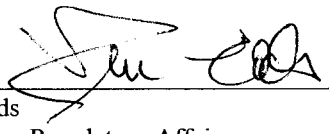
0.01 – 100 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.01	0.03

4. Conclusion

Performance of the ADVIA IMS PSA Assay on a *Bayer ADVIA*® IMS™ is equivalent to the performance of the PSA Assay on the predicate device (Immuno 1) and is within proposed specifications. No safety and effectiveness issues have been raised



12/04/02

K. Edds
Director Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2002

Kenneth T. Edds, Ph.D.
Regulatory Affairs Manager
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Re: k022177
Trade/Device Name: PSA (Prostate Specific Antigen) Assay for the ADVIA® IMS™
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LTJ; JIS
Dated: December 5, 2002
Received: December 6, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022177

Device Name: PSA (Prostate Specific Antigen) Assay for the ADVIA® IMS™

Indications for Use:

The *Bayer ADVIA® IMS* PSA assay is an *in vitro* diagnostic device intended to quantitatively measure prostate specific antigen (PSA) in human serum. This assay is indicated for the measurement of serum PSA as an aid in management (monitoring) of prostate cancer patients. PSA values obtained using the *Bayer* ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

P Keens for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022177